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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,282	12/19/2001	Mark W. Bleyer	3433-333	5918

7590 07/13/2004

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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,282	BLEYER ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *9 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-24 and 26-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of species: porcine based tissue submucosa, tissue submucosa from alimentary tissue, tantalum, spherical shaped device, and an injectable shape, in the response filed April 2004 is acknowledged. Applicant's traversal is that the restriction is not clear and too extensive, that a search of prior art would be overlapped, and that there is no undue burden to do a search of all of the species as listed in the claims. The traversal has been considered and is found partially persuasive with respect to a prior art search of a radiopaque marker selected from tantalum, barium and bismuth, and of shapes such as gel-like formulation, injectable formulation, membrane-type formulation, powdery formulation. However, a restriction of other species as listed in the claims remain because the presently pending clams list numerous species of tissue submucosas, other radiopaque markers, and biomaterials. As such, not only a prior art search has to be conducted for each of the species, a prior art consideration and/or examination of arts relevant to the claimed inventions as a whole would be unduly burdensome to the examiner. Furthermore, the examiner acknowledges that the species restriction would facilitate the progress of the examination of the main invention, and that should the elected species be free of any prior art, a search of the other species would be continued. Thus, the species restriction remains proper and made final. Claims 9 and 25 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 1-8, 10-24, 26-35 are pending for examination.

The cross-reference information needs to be updated to reflect the current status of the parent application of this-as-filed application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-24, 26-29, 32, and 33 are rejected under 35 U.S.C 103(a) as being unpatentable over any of Kropp *et al.* (Urology, 46, 3, pp. 396-400, 1995, Whitson

et al., US Pat No. 5,997,575, and Bonadio *et al.* (US Pat No. 5,942,496), taken with Berg (US Pat No. 6,048,362) and Martin *et al.* (US Pat No. 6,042,605).

Kropp *e al.,* Whitson *et al.* and Bonadio *et al.* all teach a implantable collagenous biomaterial comprising porcine derived small intestine submucosa (SIS), and a biological or known pharmacological agent dispersed therein (Kropp, entire document, Whitson, entire document, Bonadio, column 30, last paragraph. Regarding the types of formulation of the implantable biomaterial as cited in claim 16, for example, the formulations including gel-like formulation, injectable formulation, membrane-type formulation, powdery formulation are all taught by the cited references (Kropp and Whitson membrane-type formulation, injectable, gel-like, dry, solid, and powdery formulation, Bonadio, column 14). While each of the cited references teaches at least one of the shapes cited in the elected species of the claimed invention, it would have been obvious for one of ordinary skill in the art as matter of design choice to construct the biomaterial in any shape known in the prior art so long as the shape of the biocompatible material is compatible with an instrument used in grafting medical art for assisting with the placement of the biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record.

Kropp *e al.,* Whitson *et al.* and Bonadio *et al.* do not teach an incorporation of a radiopaque marker including barium, tantalum powder, and bismuth on the collagenous material or SIS.

However, at the time the invention was made, both Berg and Martin *et al.* teach the advantages of employing a radiopaque marker on an implantable biomaterial. For example, Martin teaches that one or more radio-opaque metallic fibers, such as gold, platinum, platinum-tungsten, palladium, platinum-iridium, rhodium, tantalum, or alloys or composites of these metals like may be incorporated in a grafting device or biomaterial, to allow fluoroscopic visualization of the grafting device or biomaterial (column 12). In addition, Berg teaches that in order for a physician to view the graft structure during an implantation procedure, a radiopaque marker, such as barium, bismuth, or tungsten is added to the implantable material so as to make the implantable biomaterial radiopaque enough to be clearly visible on a fluoroscope when inside the patient's body.

It would have been obvious for one of ordinary skill in the art to have incorporated any radiopaque marker known in the prior art including barium barium, tantalum powder, and bismuth on the collagenous material or SIS of Kropp *e al.,* Whitson *et al.* and Bonadio *et al.* One of ordinary skill in the art would have been motivated to have incorporated any radiopaque marker known in the prior art on to the biomaterial of Kropp *e al.,* Whitson *et al.* and Bonadio *et al.* because both Berg and Martin *et al.* teach the advantages of employing a radiopaque marker on an implantable biomaterial, whereby visualization of any graft material can be enhanced as a result of the incorporation. To the extent the claimed invention is directed to any minor modification including where the radiopaque marker is added onto the tissue submucosa of the cited references, such modification would have been obvious variants

or obvious matter of design choice to one of ordinary skill in the art over the combined prior art of record as a whole.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 1-8, 10-24, 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Badylak *et al.* (WO 96/24661), Badylak 2 (WO 96/25179), Cook *et al.* (WO 98/22158), Fearnot (US 6,358,284), Badylak 3 (US 2004/0078076) taken with Berg (US Pat No. 6,048,362), Martin *et al.* (US Pat NO. 6,042,605), and Scarborough (US Pat No. 5,676,146).

Badylak *et al..,* Badylak 2., Cook *et al.,* Fearnot, and Badylak 3 all teach a implantable collagenous biomaterial comprising a tissue submucosa from at least one of an alimentary, submucosa, and a biological or pharmacological agent dispersed therein (Badylak *et al.,* entire document, especially pages 5-8; Badylak. 2, entire document, pages 5-8, Cook *et al.,* entire document, especially, pages 8-10, Fearnot, columns 2, 3, 6, 7, 18). Regarding the types of formulation of the implantable biomaterial as cited in claim 16, for example, the formulations including, fluidized, comminuted, liquefied, suspended, ground, sheared, solid, gel-like, injectable, membrane-type, and powdery formulation are all taught by the cited references and are well known in the prior art of record (pages 15-21 of Cook *et al.,* for example, Badylak. 2, page 9, for example). Each of the cited references also teach at least one of the shapes cited in the Markush group of the claimed invention, and to the extent that at least one of the cited shape is not described in each of the cited references, it would have been obvious for one of

ordinary skill in the art as matter of design choice to construct the biomaterial in any shape known in the prior art so long as the shape of the biocompatible material is compatible with an instrument used in grafting medical art for assisting with the placement of the biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record. Regarding the functional limitation citing the endotoxin level less than 12 endotoxin units per gram, Badylak *et al.,* Badylak.2., and Cook *et al.* all teach sterilization techniques to ensure that the tissue submucosa used for grafting are sterilized and free of bacterial contaminants, *e.g.,,* Badylak *et al.,* pages 8, 19, 20, 32, and 33; Badylak. 2, pages 10-11, Cook *et al.,* pages 10-15, Fearnot, claims on column 18, Badylak 3, claims. Absent evidence to the contrary, and as evidenced by the disclosure of Fearnot and Badylak 3, the tissue submucosa based biomaterials as prepared in Badylak *et al..,* Badylak.2., and Cook *et al.* have all of the functional properties cited in the claims.

The primary references do not teach an incorporation of a radiopaque marker barium, tantalum powder, and bismuth on the collagenous material or SIS.

However, at the time the invention was made, both Berg and Martin *et al.* teach the advantages of employing a radiopaque marker on an implantable biomaterial. For example, Martin teaches that one or more radio-opaque metallic fibers, such as gold, platinum, platinum-tungsten, palladium, platinum-iridium, rhodium, tantalum, or alloys or composites of these metals like may be incorporated in a grafting device or biomaterial, to allow fluoroscopic visualization of the grafting device or biomaterial (column 12).

Berg teaches that in order for a physician to view the graft structure during an implantation procedure, a radiopaque marker, such as barium, bismuth, or tungsten is added to the implantable material so as to make the implantable biomaterial radiopaque enough to be clearly visible on a fluoroscope when inside the patient's body. In addition, Scarborough teaches an implant containing a resorbable radiopaque marker that enables the position and/or orientation of the implant to be readily determined by x-ray or other radiographic technique following its implantation in the body.

It would have been obvious for one of ordinary skill in the art to have incorporated any radiopaque marker known in the prior art including barium, tantalum powder, and bismuth on the collagenous material or SIS of any of the exemplified primary references. One of ordinary skill in the art would have been motivated to have incorporated any radiopaque marker known in the prior art onto a tissue submucosa based biomaterial. because both Berg and Martin *et al.* teach the advantages of employing a radiopaque marker on an implantable biomaterial, whereby visualization of any graft material can be enhanced as a result of the incorporation. To the extent the claimed invention is directed to any minor modification including where the radiopaque marker is added onto the tissue submucosa of the cited references, such modification would have been obvious variants or obvious matter of design choice to one of ordinary skill in the art over the combined prior art of record as a whole.

Thus, the claimed invention as a whole was *prima facie* obvious.

Copies of the references that were cited in the parent application will not be provided to applicants unless requested.

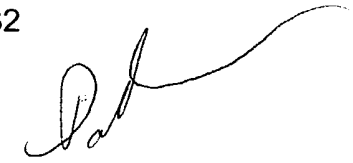
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
Art Unit: 1632



DAVE T. NGUYEN
PRIMARY EXAMINER